

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RLL-466WO	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/IB2004/002654	International filing date (day/month/year) 13/08/2004	(Earliest) Priority Date (day/month/year) 14/08/2003
Applicant RANBAXY LABORATORIES LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

PHARMACEUTICAL COMPOSITIONS OF NATEGLINIDE AND A HIGH AMOUNT OF A WATER-SOLUBLE FILLER

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

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Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The present invention relates to pharmaceutical compositions of Nateglinide with 50-70% of water-soluble filler such as lactose alone or in combination with a channeling agent such as sodium chloride or compressible sugar. These compositions may have a dissolution profile wherein at least 70% by weight of Nateglinide is released within 45 minute period.

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A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K9/20 A61K31/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,Y	EP 0 965 339 A (AJINOMOTO KK) 22 December 1999 (1999-12-22) the whole document paragraphs '0002!', '0005!', '0006!', '0015!', '0020!', '0022!', '0028!', '0032!', '0034!; claims 1,3,4,7,8,11,12; table 1	1-31
X,Y	EP 1 258 249 A (AJINOMOTO KK) 20 November 2002 (2002-11-20) the whole document examples 7,10,20	1-31
X,Y	US 2003/036479 A1 (AYLWARD PETER T ET AL) 20 February 2003 (2003-02-20) the whole document paragraphs '0027!', '0028!', '0037!', '0039!; claims 6-8	1-31
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

30 December 2004

Date of mailing of the international search report

11/01/2005

Name and mailing address of the ISA

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,Y	US 6 559 188 B1 (ALLISON MALCOLM ET AL) 6 May 2003 (2003-05-06) cited in the application the whole document column 26, line 24 - column 27, line 55 claim 1; examples 1,4,8 -----	1-31
P,X, Y	WO 03/076393 A (NOVARTIS PHARMA GMBH ; NOVARTIS AG (CH); PARKER DAVID JOHN (US); SUTTO) 18 September 2003 (2003-09-18) example 9 -----	1-31
X,Y	XU WEI, YIN LI-FANG: "Preparation and quality investigation of nateglinide dispersible tablets" ACADEMIC JOURNAL OF GUANGDONG COLLEGE OF PHARMACY, vol. 19, no. 1, March 2003 (2003-03), pages 3-6, XP001204563 the whole document abstract -----	1-31
X,Y	HE XIAO-RONG, HU XIN, YAN XIAO-YAN: "dissolution study of tablets of nateglinide" CHIN HOSP PHARM J, vol. 23, no. 2, February 2003 (2003-02), page 82-84, XP001204565 the whole document abstract -----	1-31

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Although claims 29-31 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box II.1

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box II.2

The wording "water-soluble filler" in present claims 1, 22 and 29 relates to an extremely large number of possible compounds and has thus an obscure and unspecific meaning. For example povidone or carboxymethylcellulose calcium or HPMC or dextrin are known as binders and/or disintegrants, but can also be used as a water-soluble filler. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the compounds of claims 3-4.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 29-31 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB2004/002654

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0965339	A	22-12-1999	AU 718350 B2	13-04-2000
			AU 4965497 A	10-06-1998
			CA 2271865 A1	28-05-1998
			EP 0965339 A1	22-12-1999
			US 6143323 A	07-11-2000
			US 2003147951 A1	07-08-2003
			US 6296872 B1	02-10-2001
			US 2002028239 A1	07-03-2002
			WO 9822105 A1	28-05-1998
			JP 10194969 A	28-07-1998
			KR 2000053312 A	25-08-2000
			TW 492878 B	01-07-2002
EP 1258249	A	20-11-2002	AU 2226901 A	09-07-2001
			BR 0016801 A	24-09-2002
			CA 2395993 A1	05-07-2001
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			HU 0204109 A2	28-05-2003
			NO 20023035 A	21-08-2002
			SK 9292002 A3	08-10-2002
			US 2003021843 A1	30-01-2003
			CN 1437483 T	20-08-2003
			CZ 20022294 A3	13-11-2002
			WO 0147557 A1	05-07-2001
			PL 356300 A1	28-06-2004
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WO 03076393	A	18-09-2003	CA 2478599 A1	18-09-2003
			WO 03076393 A1	18-09-2003
			EP 1483232 A1	08-12-2004